



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 20, 2020

Matthew Brooks
Agent
SpectraShield Technologies, LLC
4835 E. Cactus Road #320
Scottsdale, AZ 85258

Subject: PRIA Label Amendment – Add Virus Claims
Product Name: SpectraKill RTU
EPA Registration Number: 90748-1
Application Date: July 23, 2020
Decision Number: 564884

Dear Mr. Brooks:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is (small non-enveloped, large non-enveloped, enveloped).
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against (Feline Calicivirus, Human Rhinovirus, Norovirus) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Wanda Henson by phone at (703) 308-6345 or via email at henson.wanda@epa.gov

Sincerely,



Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

[FRONT PANEL]



ACCEPTED
10/20/2020
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 90748-1

[ABNS: SPECTRAVET; SPECTRACARE; SPECTRAAG]

ACTIVE INGREDIENTS

Table with 2 columns: Ingredient Name and Percentage. Includes Hydrogen Peroxide (5.350%), Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride (0.117%), and INERT INGREDIENTS (94.533%).

TOTAL.....100.000 %

EPA Reg. No. 90748-1 EPA Est. No.62847-IN-1

Net Contents: [24oz, 32 oz, 1 gal, 5 gals, 55gals, 275 gals and 330 gals]

KEEP OUT OF REACH OF CHILDREN
CAUTION PRECAUCION
{See [left] {back} {side} {right} {insert} {panel} {of label}} {below} for {additional} {precautionary statements}{and}{or}{first aid}}.

HMIS Rating System: Health – 1 Flammability – 0 Reactivity – 0

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance. Consult a doctor for treatment advice.
IF SWALLOWED: If you feel unwell, call poison control center or consult a doctor immediately for treatment advice. Do not induce vomiting. Do not give anything by mouth to an unconscious person.
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or consulting a doctor. For emergency information on product [product, use, etc.], call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. Other times, call the poison control center 1-800-222-1222. Further questions, call Professional Emergency Resource Services at 1-800-633-8253.

Manufactured for:
SpectraShield™ Technologies, LLC
4835 E Cactus Rd., #320
Scottsdale, AZ 85254

PRECAUTIONARY STATEMENT

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution –Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARD

Do not store near heat or open flame. Do not mix with other oxidizers, soap, or anionic materials.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Non-refillable container. Store only in original container. Do not reuse empty container. Store pesticides away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use. Store in a cool, dry, place. Open dumping is prohibited. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use. Keep from freezing.

Container Disposal: Fill container $\frac{1}{4}$ full with water and re-close the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap container and put in trash or offer for recycling if available.

One Step Disinfectant Germicidal Detergent and Deodorant

SpectraKill – RTU is a proven one-step disinfectant – cleaner – fungicide- virucide- bactericide- and deodorizer that is effective in the presence of 5% serum contamination. SpectraKill – RTU is perfect for use on hard, non-porous surfaces in:

- Hospitals, medical and dental offices, outpatient clinics, nursing homes, healthcare facilities, physician offices, patient care rooms, emergency rooms, exam rooms, operating rooms, radiology rooms, isolation wards, recovery rooms, labs, hospices, surgical centers, dialysis centers, cancer centers, exercise & physical therapy centers
- EMS and fire departments, ambulance services, emergency vehicles, equipment, fire trucks, police cars, police stations, correctional facilities, jails, prisons, penitentiaries
- Schools, colleges, universities, day care centers, classrooms, laboratories, athletic facilities, locker rooms, exercise facilities, gyms, restrooms, shower rooms
- Hotels, motels, resorts, cruise ships, health clubs, spas, tanning salons/ beds,
- Basements, cellars, bedrooms, attics, living rooms, porches, crawl spaces.

FOR USE AS A DISINFECTANT AGAINST THE FOLLOWING ORGANISMS WITH A 2 MINUTE CONTACT TIME:

Staphylococcus aureus [(ATCC 6538)] [Staph]
Salmonella enterica [(ATCC 10708)] [Salmonella]
Pseudomonas aeruginosa [(ATCC 15442)]

FOR USE AS A FUNGICIDE AGAINST THE FOLLOWING ORGANISMS WITH A 2 MINUTE CONTACT TIME:

T. mentagrophytes [(ATCC 9533)]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For Use as a ([Disinfectant] [Fungicide] [Deodorizer]): Apply product to hard, inanimate, non-porous surfaces, thoroughly wetting the surface, with a cloth, mop, sponge or spray. For visibly soiled areas, a preliminary cleaning is required. The surface must be thoroughly rinsed with portable water before application. If sprayed, use a coarse spray setting, spray 10" to 18" inches from the surface and do not breathe the spray. Keep the surfaces wet for 2 minutes. Product must be reapplied if it dries out or becomes diluted by any liquid during the 2 minute contact time. A potable water rinse is required after application on food contact surfaces.

VIRUCIDAL ACTIVITY – To eliminate viruses listed on table below on visibly clean hard non-porous surfaces, apply the product and make sure the surface is completely visible wet for 10 minutes. This product is virucidal against Rhinovirus and Norovirus (Feline Calicivirus Surrogate). When used as directed, this product has been demonstrated to provide disinfection efficacy on hard non porous surfaces against the following viruses;

Virus	ATCC #
Rhinovirus	VR-283
Norovirus (Feline Calicivirus Surrogate)	VR-782

Institutional/Medical Premises and equipment*

*This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

{ANIMAL PREMISES :}

(Note to reviewer: *The following statement will be used on all labels with use directions for animal premises except, terrariums, small animal cages, and reptile tanks.*)

Prior to use of this product, remove all animals {poultry} and feeds from [{premises} {areas to be treated}], animal transportation vehicles {(trucks, cars)}, and enclosures {(coops, crates, kennels, stables)}. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other surfaces of facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean surfaces with soap or detergent and rinse with water.

FOR USE AS AN ANIMAL PREMISE DISINFECTANT: Apply this product to disinfect hard, non-porous surfaces with a sponge, brush, cloth, {by immersion}, {{mechanical spray device}, {{{hand pump} {coarse}} trigger spray device}. For

spray applications, spray 6 – 8 inches from surface. Do not breathe spray.) Immerse all halters and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the use solution. Treated surfaces must remain visibly wet for 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house [(animals) {poultry} {livestock}] or employ equipment until treatment has been absorbed, set or dried.

Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains and waterers and other treated equipment which can contact food or water with soap or detergent, and rinse with potable water before reuse.

HATCHERIES: Use to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard, non-porous surfaces. Leave all treated surfaces visibly wet for 10 minutes or more. Allow to air dry.

VEHICLES: To clean hard, non-porous surfaces on vehicles including mats, crates, cabs, and wheels, use 1 oz. Apply use solution to treat hard, non-porous surfaces on vehicles. Leave treated surfaces visibly wet for 10 minutes. Allow to air dry.

DRESSING {/RENDERING} PLANT: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate surfaces with this product and scrub to loosen all soils. Surfaces must remain visibly wet for 10 minutes, and then be thoroughly rinsed with potable water before operations are resumed.

TERRARIUM AND SMALL ANIMAL CAGE AND CAGE FURNITURE DISINFECTION:

{Animals frequently defecate on rocks and other hard, non-porous cage furniture items inside your terrarium. This can result in high bacteria and ammonia levels that can lead to possible infection/disease in your animals. When used regularly, this product can eliminate these high bacteria/ammonia levels in your cage and on your cage furniture items.} (Do not use on porous rocks, hot rocks, and driftwood.)

1. Remove all animals.
2. Thoroughly clean surfaces and objects {caves, cage furniture, feeding and watering dishes, and appliances} including the substrate in the terrarium or cage with soap or detergent and rinse with water.
3. Saturate all hard, non-porous surfaces {such as floors, walls, cages and other washable hard, non-porous surfaces} to disinfect.
4. Apply by cloth, mop, brush, sponge, {by immersion,} {auto scrubber,} {{mechanical spray device,} {{{hand pump} {coarse}} trigger spray device}. For spray applications, spray 6-8 inches from surface. Do not breathe spray.) Rub with brush, cloth, or sponge. For smaller surfaces, use a trigger spray bottle to spray surfaces with solution.
5. Allow surfaces to remain visibly wet for a period of 10 minutes.
6. Saturate gravel as above and let stand for 10 minutes. Place in bucket of clean water and swirl for 15-30 seconds. Thoroughly air dry before returning to terrarium.
7. Thoroughly scrub all treated surfaces (except gravel) with soap or detergent and rinse with potable water before reuse.
8. Do not return animals to the habitat until it is dry and ventilated.
9. Clean terrarium at least once weekly or more as needed. Change cloth, sponge or towels frequently to avoid redeposition of soil.
10. Prepare a fresh solution daily or more often if use solution becomes visibly soiled or dirty.

Note: Substrates for desert terrariums (i.e. gravel) must be completely dry before returning to terrarium to avoid high humidity levels. Always replace substrate if a foul odor persists. Do not apply this product directly onto the small animal. If this product comes into contact with the small animal's skin, then immediately wash the material off of the animal with lukewarm water. If the small animal ingests this product, contact your veterinarian immediately.

REPTILE TANK CLEANING AND DISINFECTION DIRECTIONS: Remove all reptiles from the enclosure tank prior to cleaning and disinfecting. Remove all litter or drippings from surfaces. Empty all equipment used for feeding or watering reptiles. Thoroughly clean surfaces with soap or detergent and rinse with water. Apply to hard, non-porous surfaces of the enclosure tank. Apply by cloth, mop, brush, sponge, by immersion, auto scrubber, mechanical spray device, hand pump coarse trigger spray device. For spray applications, spray 6-8 inches from surface. Do not breathe spray. Allow surfaces to remain visibly wet for 10 minutes. Wipe dry with a paper towel. Rinse surfaces that come in contact with food with potable water before reuse. Allow the enclosure tank to ventilate for a minimum of 10-15 minutes before replacing the reptiles. Prepare a fresh solution daily or when visibly dirty.

Note: Do not apply this product directly onto the reptile. If this product comes into contact with the reptile's skin, then immediately wash the material off of the animal with lukewarm water. If the reptile ingests this product, contact your veterinarian immediately.

Emerging Viral Pathogen Claims:

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Feline Calicivirus, Strain F-9 (ATCC VR-782), surrogate for Norovirus
Large, non-enveloped virus	Feline Calicivirus, Strain F-9 (ATCC VR-782), surrogate for Norovirus
Small, non-enveloped virus	Human Rhinovirus 16, strain 11757 (ATCC VR-283) Feline Calicivirus, Strain F-9 (ATCC VR-782), surrogate for Norovirus

SpectraKill RTU has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore SpectraKill RTU can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. SpectraKill RTU kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against norovirus on hard non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

WARRANTY STATEMENT

Spectrashield Technologies LLC warrant that this product conforms to chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather condition, presence of other materials or the manner of use or application, all of which are beyond the control of Spectrashield Technologies LLC. To the extent consistent with applicable law, Spectrashield Technologies LLC shall not be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. To the extent consistent with applicable law, the exclusive remedy of any buyer or user if this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall not exceed the purchase price paid for this product or at Spectrashield Technologies LLC election, the replacement of this product. SpectraShield Technologies LLC MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

Marketing statements for SpectraKill RTU, 90748-1:

Kills 99.9% bacteria, viruses, fungi, allergens, and germs

Virucide

Disinfectant

Dual Active Ingredients

Stabilized Hydrogen Peroxide

Kills Norovirus

Kills Rhinovirus

Kills Fungi

Inhibits growth of bacteria, viruses, fungi, and germs

Bactericide

Fungicide

Eliminates Viruses, Bacteria, Fungi, Allergens, and Odor

Residential, Commercial, Industrial

Multiple use(s), application(s)

ICONS/Pictograms:

Hospital, University, Schools, Commercial Building, Bath, Restroom, Homes, Residential, Apartments, Warehouses, Offices, Barns, Industrial Buildings, Apartments, Retail Space, Arenas, EMS, Fire House, Police Station, Ambulance

[Additional Optional Language and Graphics]

American Made (with American Flag Icon)
Veteran Owned/Managed
Hydrogen Peroxide Based
Odorless
No Fragrances
No Bleach
No Chlorine
No Phenols
No Phosphates
Ready To Use (RTU)
Service Disable Veteran Owned Small Business (SDVOSB)
No residue
No harsh chemicals, fumes, or off-gassing
Eliminates pet odors
Eliminates urine and other strong pet odors
Eliminates odors at the source (No Masking)
Safe for most hard non-porous surfaces
Deodorizer
Multipurpose Disinfectant and Cleaner
Easy to Use
Patent Pending
Broad Spectrum
-eliminates odors on floors, walls, ceilings, fabrics, automobile interiors, kennels, furniture, hospital environments, anywhere there may be an odor or where odors from bacteria, mold and mildew exist.
Cleaner, healthier work environment for patients, staff, and visitors.
Cost-effective
American Made
Manufactured in the USA
Eco Friendly
Non-food contact surface
Neutral to animal olfactory
Transportation crates & vehicles
Sustainable, breaking down into water and oxygen
Disinfectant
Virucide
Designed for use on hard non-porous surfaces made from: Vinyl, painted surfaces, stainless steel, chrome, glazed porcelain, glazed ceramic, plastic, aluminum, laminated surfaces, glass, tile, grout, work stations

Optional Graphics



